

JUL 09 2007  
 APPLICATION NUMBER  
 FILING DATE

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Application Number	10/502,359
Filing Date	November 30, 2004
First Named Inventor	Luis Enjuanes SANCHES <i>et al.</i>
Examiner Name	Louise Wang Zhiying HUMPHREY
Attorney Docket Number	704621-2001

[illegible][illegible]

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
/L.H./	International Preliminary Examination Report of WO 01/39797 dated March 27, 2002
/L.H./	First Office Action from EP Application 04 007 406.4-1223, dated November 7, 2005
/L.H./	Enjuanes et al., " <i>Coronavirus derived expression systems</i> ," 88 JOURNAL OF BIOTECHNOLOGY 183-204 (2001)
/L.H./	Yount et al., " <i>Systematic Assembly of a Full-Length Infections cDNA of Mouse Hepatitis Virus Strain A59</i> ," 72(21) JOURNAL OF VIROLOGY 11065-11078 (2002)
/L.H./	St-Jean et al., " <i>Genetic evolution of human coronavirus OC43 in neural cell culture</i> ," X INT. NIDOVIRUS SYMP. - COLORADO SPRINGS - USA, June 25-30, 2005

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A72085715.1

### THIRD INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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/L.H./	Almazán et al., "Identification of essential genes as a strategy to select a SARS candidate vaccine using a SARS-VOV infectious cDNA clone," X. INT. NIDOVIRUS SYMP. COLORADO SPRINGS, USA, June 25-30, 2005
/L.H./	Glossary term "Clone," IN LEWIN: GENES VII NY: OXFORD UNIV. PRESS 955 (2000)
/L.H./	Expert Declaration of Thiel
/L.H./	St-Jean et al., "Recovery of a neurovirulent human coronavirus OC43 from an infectious cDNA clone," 80 J. VIROL. 3670-4 (April 2006)
/L.H./	Almazán et al., "Construction of a severe acute respiratory syndrome coronavirus infectious cDNA clone and a replicon to study coronavirus RNA synthesis," 80(21) J. VIROL. 1-7 (November 2006)
/L.H./	Almazán et al., "The nucleoprotein is required for efficient coronavirus genome replication," 78 J. VIROL. 12683-8 (November 2004)

Examiner Signature	/Louise Humphrey/	Date Considered	09/06/2007
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11/30/04

Substitute for form 1449A/PTO &amp; 1449B/PTO

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 6

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Attorney Docket Number	033644-003

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
/L.H./	5,288,641		Roizman	02-22-1994
↓	5,501,979		Geller et al.	03-26-1996
	5,585,096		Martuza et al.	12-17-1996
	5,658,724		DeLuca	08-19-1997
↓	5,776,745		Ketner et al.	07-07-1998
	6,277,621	B1	Horsburgh et al.	08-21-2001

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS						
					Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec
/L.H./	0 453 242	A1	Europe	10-23-1991							
↓	WO 01/39797		PCT	06-07-2001							
	WO 97/34008		PCT	09-18-1997							
	WO 97/30732		PCT	08-28-1997							
	WO 97/05263		PCT	02-13-1997							
	WO 99/06582		PCT	02-11-1999							
	WO 99/43842		PCT	09-02-1999							
	WO 96/26267		PCT	08-29-1996							
	WO 96/15779		PCT	05-30-1996							
	WO 96/04394		PCT	02-15-1996							
	WO 95/03400		PCT	02-02-1995							
	WO 90/09441		PCT	08-23-1990							
	2109189	A1	Spain	01-01-1998				X			
	WO 01/44458	A2	PCT	06-21-2001				X			
	WO 00/49168	A2	PCT	08-24-2000				X			
	1008652	A1	Europe	06-14-2000				X			
	36 21 537	A1	Germany		X						
↓	34 03 753	A1	Germany		X						
	197 32 593	A1	Germany		X						

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/L.H./	P. AHLQUIST et al., "Multicomponent RNA Plant Virus Infection Derived From Cloned Viral cDNA", Proc. Natl. Acad. Sci. USA, Nov. 1984, pp. 7066-7070, Vol. 81, The National Academy of Sciences, Washington, DC
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Sheet 2 of 6

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/L.H./	F. ALMAZAN et al., "Engineering the Largest RNA Virus Genome as an Infectious Bacterial Artificial Chromosome", Proc. Natl. Acad. Sci. USA, May 2000, pp. 5516-5521, Vol. 97, No. 10, The National Academy of Sciences, Washington, DC
	F. ASCENZIONI et al., "Mammalian Artificial Chromosomes-Vectors for Somatic Gene Therapy", Cancer Letters, 1997, pp. 135-142, Vol. 118, Elsevier Science Ireland Ltd., Ireland
	M.L. BALLESTEROS et al., "Two Amino Acid Changes at the N-Terminus of Transmissible Gastroenteritis Coronavirus Spike Protein Result in the Loss of Enteric Tropism", Virology, 1997, pp. 378-388, Vol. 227, Academic Press, Inc., San Diego, CA
	M.D. BARON et al., "Rescue of Rinderpest Virus From Cloned cDNA", J. Virol., Feb. 1997, pp. 1265-1271, Vol. 71, No. 2, American Society for Microbiology, Washington, DC
	G. BILBAO et al., "Adenoviral/Retroviral Vector Chimeras: A Novel Strategy to Achieve High-Efficiency Stable Transduction in vivo", The FASEB Journal, Jul. 1997, pp. 624-634, Vol. 11, FASEB, Bethesda, MD
	J.-C. BOYER et al., "Infectious Transcripts and cDNA Clones of RNA Viruses", Virology, 1994, pp. 415-426, Vol. 198, Academic Press, Inc., San Diego, CA
	BURKE, "Special Section: Yeast Artificial Chromosome Cloning; YAC Cloning: Options and Problems", Genet. Anal. Tech. Appl., 1990, pp. 94-99, Vol. 7, No. 5, Elsevier Science Publishing Co., Inc., NY, NY
	R. CASAIS et al., "Reverse Genetics System for the Avian Coronavirus Infectious Bronchitis Virus", J. Virol., Dec. 2001, pp. 12359-12369, Vol. 75, No. 24, ASM Press, Washington, DC
	R.-Y. CHANG et al., "A cis-Acting Function for the Coronavirus Leader in Defective-Interfering RNA Replication", J. Virol., Dec. 1994, pp. 8223-8231, Vol. 68, No. 12, American Society for Microbiology, Washington, DC
	H.C. CHIOU et al., "Mutations in the Herpes Simplex Virus Major DNA-Binding Protein Gene Leading to Altered Sensitivity to DNA Polymerase Inhibitors", Virology, 1985, pp. 213-226, Vol. 145, Academic Press, Inc., San Diego, CA
	P.L. COLLINS et al., "Production of Infectious Human Respiratory Syncytial Virus From Cloned cDNA Confirms an Essential Role for the Transcription Elongation Factor From the 5' Proximal Open Reading Frame of the M2 mRNA in Gene Expression and Provides a Capability for Vaccine Development", Proc. Natl. Acad. Sci. USA, Dec. 1995, pp. 11563-11567, Vol. 92, The National Academy of Sciences, Washington, DC
	N.L. DAVIS et al., "In vitro Synthesis of Infectious Venezuelan Equine Encephalitis Virus RNA From a cDNA Clone: Analysis of a Viable Deletion Mutant", Virology, 1989, pp. 189-204, Vol. 171, Academic Press, Inc., San Diego, CA
	T.W. DUBENSKY, Jr. et al., "Sindbis Virus DNA-Based Expression Vectors: Utility For in vitro and in vivo Gene Transfer", J. Virol., Jan. 1996, pp. 508-519, Vol. 70, No. 1, American Society for Microbiology, Washington, DC
	A.P. DURBIN et al., "Recovery of Infectious Human Parainfluenza Virus Type 3 From cDNA", Virology, 1997, pp. 323-332, Vol. 235, Academic Press, Inc., San Diego, CA
	L. ENJUANES et al., "Coronaviruses and Arteriviruses", 1998, Plenum Press, New York
	L. ENJUANES et al., "Molecular Basis of Transmissible Gastroenteritis Virus Epidemiology", In The Coronaviridae, 1995, S.G. Siddell (Ed.) Plenum Press, New York, pp. 337-376
✓	I. FROLOV et al., "Alphavirus-Based Expression Vectors: Strategies and Applications", Proc. Natl. Acad. Sci. USA, Oct. 1996, pp. 11371-11377, Vol. 93, The National Academy of Sciences, Washington, DC

Examiner Signature	/Louise Humphrey/	Date Considered	09/06/2007
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# **FIRST** **INFORMATION DISCLOSURE** **STATEMENT BY APPLICANT**

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/L.H./	P.J. GAGE et al., "A cell-Free Recombination System for Site-Specific Integration of Multigenic Shuttle Plasmids Into the Herpes Simplex Virus Type 1 Genome", J. Virol., Sept. 1992, pp. 5509-5515, Vol. 66, No. 9, American Society for Microbiology, Washington, DC
	D. GARCIN et al., "A highly Recombinogenic System for the Recovery of Infectious Sendai Paramyxovirus From cDNA: Generation of a Novel Copy-Back Nondefective Interfering Virus", EMBO J., 1995, pp. 6087-6094, Vol. 14, No. 24, Oxford University Press, Oxford, UK
	U. GEIGENMÜLLER et al., "Construction of a Genome-Length cDNA Clone for Human Astrovirus Serotype 1 and Synthesis of Infectious RNA Transcripts", Feb. 1997, J. Virol., pp. 1713-1717, Vol. 71, No. 2, American Society for Microbiology, Washington, DC
	B.C. HORSBURGH et al., "Allele Replacement: An Application That Permits Rapid Manipulation of Herpes Simplex Virus Type 1 Genomes", Gene Therapy, May 1999, pp. 922-930, Vol. 6, No. 5, Stockton Press, Hampshire, UK
	B. HSUE et al., "Insertion of a New Transcriptional Unit Into the Genome of Mouse Hepatitis Virus", J. Virol., July 1999, pp. 6128-6135, Vol. 73, No. 7, American Society for Microbiology, Washington, DC
	A. IZETA et al., "Replication and Packaging of Transmissible Gastroenteritis Coronavirus-Derived Synthetic Minigenomes", J. Virol., Feb. 1999, pp. 1535-1545, Vol. 73, No. 2, American Society for Microbiology, Washington, DC
	G. KETNER et al., "Efficient Manipulation of the Human Adenovirus Genome as an Infectious Yeast Artificial Chromosome Clone", Proc. Natl. Acad. Sci. USA, June 1994, pp. 6186-6190, Vol. 91, The National Academy of Sciences, Washington, DC
	U.-J. KIM et al., "Stable Propagation of Cosmid Sized Human DNA Inserts in an F Factor Based Vector", Nucleic Acids Res., Mar. 11, 1992, pp. 1083-1085, Vol. 20, No. 5, Oxford University Press, Oxford, UK
	L. KUO et al., "Retargeting of Coronavirus by Substitution of the Spike Glycoprotein Ectodomain: Crossing the Host Cell Species Barrier", J. Virol., Feb. 2000, pp. 1393-1406, Vol. 74, No. 3, ASM Press, Washington, DC
	M.C. LAI, "The Making of Infectious Viral RNA: No Size Limit in Sight", Proc. Natl. Acad. Sci. USA, May 2000, pp. 5025-5027, Vol. 97, No. 10, The National Academy of Sciences, Washington, DC
	C.-J. LAI et al., "Infectious RNA Transcribed From Stably Cloned Full-Length cDNA of Dengue Type 4 Virus", Proc. Natl. Acad. Sci. USA, June 1991, pp. 5139-5143, Vol. 88, The National Academy of Sciences, Washington, DC
	M.M.C. LAI et al., "The Molecular Biology of Coronaviruses", Adv. Virus Res., 1997, pp. 1-100, Vol. 48, Academic Press
	M.M.C. LAI et al., "Coronavirus: How a Large RNA Viral Genome is Replicated and Transcribed", Infect. Agents Dis., 1994, pp. 98-105, Vol. 3, Nos. 2/3, Raven Press Ltd., NY
	P. LILJESTRÖM, "Alphavirus Expression Systems", Curr. Opin. Biotech., 1994, pp. 495-500, Vol. 5, Current Biology Ltd., London, UK
	P. LILJESTRÖM et al., "A New Generation of Animal Cell Expression Vectors Based on the Semliki Forest Virus Replicon", Bio/Technology, Dec. 1991, pp. 1356-1361, Vol. 9, Nature Publishing Co., Bleecker, NY
	W. LUYTJES et al., "Amplification, Expression, and Packaging of a Foreign Gene by Influenza Virus", Cell, Dec. 22, 1989, pp. 1107-1113, Vol. 59, Cell Press, Cambridge, Massachusetts
	C.W. MANDL et al., "Infectious cDNA Clones of Tick-Borne Encephalitis Virus European Subtype Prototypic Strain Neudoerfl and High Virulence Strain Hypr", J. Gen. Virol., 1997, pp. 1049-1057, Vol. 78, SGM, UK
✓	T. MANIATIS et al., "Molecular Cloning: A Laboratory Manual", 1989, Cold Spring Harbour Laboratory Press, New York

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/L.H./	P.S. MASTERS, "Reverse Genetics of the Largest RNA Viruses", <i>Advances in Virus Research</i> , 1999, pp. 245-246, Vol. 53, Academic Press, San Diego, CA
	A. MÉNDEZ et al., "Molecular Characterization of Transmissible Gastroenteritis Coronavirus Defective Interfering Genomes: Packaging and Heterogeneity", <i>Virology</i> , 1996, pp. 495-507, Vol. 217, Academic Press, Inc., San Diego, CA
	M. MESSERLE et al., "Reconstitution of a Recombinant Cytomegalovirus From Two Fragments Cloned Into Bacterial Artificial Chromosomes", <i>J. Mol. Med.</i> , 1996, pp. Vol. 74, No. 4, Abstracts B1-B11, Springer-Verlag, Berlin, Germany
	M. MESSERLE et al., "Cloning and Mutagenesis of a Herpesvirus Genome as an Infectious Bacterial Artificial Chromosome", <i>Proc. Natl. Acad. Sci. USA</i> , 1997, pp. 14759-14763, Vol. 94, The National Academy of Sciences, Washington, DC
	MONACO et al., <i>Tibtech</i> , Jul. 1994, pp. 280-286, Vol. 12
	Z. PENZES et al., "Complete Genome Sequence of Transmissible Gastroenteritis Coronavirus PUR46-MAD Clone and Evolution of the Purdue Virus Cluster", <i>Virus Genes</i> , 2001, pp. 105-118, Vol. 23, No. 1, Kluwer Academic Publishers, The Netherlands
	P. PUSHKO et al., "Replicon-Helper Systems From Attenuated Venezuelan Equine Encephalitis Virus: Expression of Heterologous Genes <i>in vitro</i> and Immunization Against Heterologous Pathogens <i>in vivo</i> ", <i>Virology</i> , 1997, pp. 389-401, Vol. 239, Academic Press, Inc., San Diego, CA
	V.R. RACANIELLO et al., "Cloned Poliovirus Complementary DNA is Infectious in Mammalian Cells", <i>Science</i> , 1981, pp. 916-919, Vol. 214, American Association for the Advancement of Science, Washington, DC
	F. RADECKE et al., "Rescue of Measles Viruses From Cloned DNA", <i>EMBO J.</i> , 1995, pp. 5773-5784, Vol. 14, No. 23, Oxford University Press, Oxford, UK
	C.M. RICE et al., "Transcription of Infectious Yellow Fever RNA From Full-Length cDNA Templates Produced by <i>in vitro</i> Ligation", <i>New Biologist</i> , Dec. 1989, pp. 285-296, Vol. 1, No. 3, W.B. Saunders Co.
	C.M. RICE et al., "Production of Infectious RNA Transcripts From Sindbis Virus cDNA Clones: Mapping of Lethal Mutations, Rescue of a Temperature-Sensitive Marker, and <i>in vitro</i> Mutagenesis to Generate Defined Mutants", <i>J. Virol.</i> , Dec. 1987, pp. 3809-3819, Vol. 61, No. 12, American Society for Microbiology, Washington, DC
	C.M. RICE et al., "Synthesis, Cleavage, and Sequence Analysis of DNA Complementary to the 26 S Messenger RNA of Sindbis Virus", <i>J. Mol. Biol.</i> , 1981, pp. 315-340, Vol. 150, Academic Press Inc., London, UK
	N. RUGGLI et al., "Nucleotide Sequence of Classical Swine Fever Virus Strain Alfort/187 and Transcription of Infectious RNA From Stably Cloned Full-Length cDNA", <i>J. Virol.</i> , June 1996, pp. 3478-3487, Vol. 70, No. 6, American Society for Microbiology, Washington, DC
	Y. SAEKI et al., "Herpes Simplex Virus Type 1 DNA Amplified as Bacterial Artificial Chromosome in <i>Escherichia coli</i> : Rescue of Replication-Competent Virus Progeny and Packaging of Amplicon Vectors", <i>Human Gene Therapy</i> , Dec. 10, 1998, pp. 2787-2794, Vol. 9, Mary Ann Liebert, Inc., Larchmont, NY
	C.M. SÁNCHEZ et al., "Targeted Recombination Demonstrates that the Spike Gene of Transmissible Gastroenteritis Coronavirus is a Determinant of its Enteric Tropism and Virulence", <i>J. Virol.</i> , Sept. 1999, pp. 7607-7618, Vol. 73, No. 9, ASM Press, Washington, DC
✓	C.M. SÁNCHEZ et al., "Antigenic Homology Among Coronaviruses Related to Transmissible Gastroenteritis Virus", <i>Virology</i> , 1990, pp. 410-417, Vol. 174, Academic Press, Inc., San Diego, CA

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/L.H./	C.M. SÁNCHEZ et al., "Genetic Evolution and Tropism of Transmissible Gastroenteritis Coronaviruses", <i>Virology</i> , 1992, pp. 92-105, Vol. 190, Academic Press, Inc., San Diego, CA
	S.G. SAWICKI et al., "Coronavirus Transcription: Subgenomic Mouse Hepatitis Virus Replicative Intermediates Function in RNA Synthesis", <i>J. Virol.</i> , Mar. 1990, pp. 1050-1056, Vol. 64, No. 3, American Society for Microbiology, Washington, DC
	M.J. SCHNELL et al., "Infectious Rabies Viruses From Cloned cDNA", <i>EMBO J.</i> , Sept. 15, 1994, pp. 4195-4203, Vol. 13, No. 18, Oxford University Press, Oxford, UK
	P.B. SETHNA et al., "Coronavirus Subgenomic Minus-Strand RNAs and the Potential for mRNA Replicons", <i>Proc. Natl. Acad. Sci. USA</i> , July 1989, pp. 5626-5630, Vol. 86, The National Academy of Sciences, Washington, DC
	H. SHIZUYA et al., "Cloning and Stable Maintenance of 300-Kilobase-Pair Fragments of Human DNA in <i>Escherichia coli</i> Using an F-Factor-Based Vector", <i>Proc. Natl. Acad. Sci. USA</i> , Sept. 1992, pp. 8794-8797, Vol. 89, The National Academy of Sciences, Washington, DC
	S.G. SIDDELL, <i>The Coronaviridae</i> , 1995, Plenum Press, New York
	C. SMERDOU et al., "Non-Viral Amplification Systems for Gene Transfer: Vectors Based on Alphaviruses", <i>Curr. Opin. Mol. Therap.</i> , 1999, pp. 244-251, Vol. 1, No. 2, Current Drugs Ltd., London, UK
	R.R. SPAETE et al., "Insertion and Deletion Mutagenesis of the Human Cytomegalovirus Genome", <i>Proc. Natl. Acad. Sci. USA</i> , Oct. 1987, pp. 7213-7217, Vol. 84, The National Academy of Sciences, Washington, DC
	M. TANIGUCHI et al., "Specific Suppressive Factors Produced by Hybridomas Derived From the Fusion of Enriched Suppressor T Cells and A T Lymphoma Cell Line", <i>J. Exp. Med.</i> , 1978, pp. 373-382, Vol. 148, The Rockefeller University Press, NY, NY
	V. THIEL et al., "Infectious RNA Transcribed <i>in vitro</i> From a cDNA Copy of the Human Coronavirus Genome Cloned in Vaccinia Virus", <i>J. Gen. Virol.</i> , 2001, pp. 1273-1281, Vol. 82, Society for General Microbiology, Great Britain
	R.G. VAN DER MOST et al., "Coronavirus Replication, Transcription, and RNA Recombination", <i>In The Coronaviridae</i> , 1995, pp. 11-31, S.G. Siddell (Ed.), Plenum Press, New York
	K. WANG et al., "Complete Nucleotide Sequence of Two Generations of a Bacterial Artificial Chromosome Cloning Vector", <i>BioTechniques</i> , Dec. 1997, pp. 992-994, Vol. 23, No. 6
	S.-S. WOO et al., "Construction and Characterization of a Bacterial Artificial Chromosome Library of <i>Sorghum bicolor</i> ", <i>Nucleic Acids Res.</i> , 1994, pp. 4922-4931, Vol. 22, No. 23, Oxford University Press, Oxford, UK
	X. YANG et al., "Homologous Recombination Based Modification in <i>Escherichia coli</i> and Germline Transmission in Transgenic Mice of a Bacterial Artificial Chromosome", <i>Nature Biotechnology</i> , Sep. 1997, pp. 859-865, Vol. 15, Nature America Inc., NY, NY
	X. ZHANG et al., "Coronavirus Leader RNA Regulates and Initiates Subgenomic mRNA Transcription Both <i>in trans</i> and <i>in cis</i> ", <i>J. Virol.</i> , Aug. 1994, pp. 4738-4746, Vol. 68, No. 8, American Society for Microbiology, Washington, DC
	International Search Report, 5/19/03
↓	ALONSO, S., IZETA, A., SOLA, I. AND ENJUANES, L., Transcription regulatory sequences and mRNA expression levels in the coronavirus transmissible gastroenteritis virus. <i>J. Virol.</i> , (2002), pp. 1293-1308, Vol. 76.

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/L.H./	IZETA, A., SMERDOU C., ALONSO, S., PENZES, Z., MÉNDEZ, A., PLANA-DURÁN, J. AND ENJUANES, L., Replication and packaging of transmissible gastroenteritis coronavirus-derived synthetic minigenomes. J. Virol., (1999), pp. 1535-1545, Vol. 73.
/L.H./	SÁNCHEZ, C. M., IZETA, A., SÁNCHEZ-MORGADO, J. M., ALONSO, S., SOLA, I., BALASCH, M., PLANA-DURÁN, J. AND ENJUANES, L., Targeted recombination demonstrates that the spike gene of transmissible gastroenteritis coronavirus is a determinant of its enteric tropism and virulence. J. Virol., (1999), pp. 7607-7618, Vol. 73

Examiner Signature	/Louise Humphrey/	Date Considered	09/06/2007
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## SECOND INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number

10/502.359

Filing Date

July 23, 2004

**First Named Inventor**

Luis Enjuanes Sanchez et al.

**Examiner Name**

Attorney Docket Number

033644-003

**U.S. PATENT DOCUMENTS**

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## FOREIGN PATENT DOCUMENTS

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## NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
/L.H./	GODET, MURIELLE ET AL., "Major Receptor-Binding and Neutralization Determinants Are Located within the Same Domain of the Transmissible Gastroenteritis Virus (Coronavirus) Spike Protein," Jnl. of Virology, Dec. 1994, pp. 8008-8016, Vol. 68, No. 12, American Society for Microbiology
/L.H./-	KOLB, ANDREAS F. ET AL., "Identification of residues critical for the human coronavirus 229E receptor function of human aminopeptidase N," Jnl. of General Virology, 1997, pp. 2795-2802, Vol. 78, Great Britain
/L.H./	KREMPL, CHRISTINE ET AL., "Point Mutations in the S Protein Connect the Sialic Acid Binding Activity with the Enteropathogenicity of Transmissible Gastroenteritis Coronavirus," Jnl. of Virology, Apr. 1997, pp. 3285-3287, Vol. 71, No. 4, American Society for Microbiology
/L.H./	SALANUEVA, INIGO J. ET AL., "Structural Maturation of the Transmissible Gastroenteritis Coronavirus," Jnl. of Virology, Oct. 1999, pp. 7952-7964, Vol. 73, No. 10, American Society for Microbiology
/L.H./	GRITSUN, T.S. ET AL., "Infectious Transcripts of Tick-Borne Encephalitis Virus, Generated in Days by RT-PCR," Virology, 1995, pp. 611-618, Academic Press, Inc.

Examiner Signature	/Louise Humphrey/	Date Considered	09/26/2007
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<b>SECOND INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <small>(use as many sheets as necessary)</small>		<b>Complete if Known</b>			
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/L.H./	HEROLD, J. ET AL., "A Strategy for the Generation of Infectious RNAs and Autonomously Replicating RNAs Based on the HCV 229E Genome," Adv. Exp. Med. Biol., 1998, pp. 265-268, Vol. 440, Plenum Press, New York
	HURRELBRINK, ROBERT J. ET AL., "Characterization of infectious Murray Valley encephalitis virus derived from a stably cloned genome-length cDNA," J. Gen. Virology, 1999, pp. 3115-3125, Vol. 80, Great Britain
	KAPOOR, MINI ET AL., "Synthesis and characterization of an infectious dengue virus type-2 RNA genome (New Guinea C strain)," Gene, 1995, pp. 175-180, Vol. 162, Elsevier Science B.V.
	MENDEZ, ERNESTO ET AL., "Infectious Bovine Viral Diarrhea Virus (Strain NADL) RNA from Stable cDNA Clones: a Cellular Insert Determines NS3 Production and Viral Cytopathogenicity," J. Virology, June 1998, pp. 4737-4745, Vol. 72, No. 6, Amer. Soc. For Microbiology
	MOORMANN, R.J.M. ET AL., "Infectious RNA Transcribed from an Engineered Full-Length cDNA Template of the Genome of a Pestivirus," J. Virology, Feb. 1996, pp. 763-770, Vol. 70, No. 2, Amer. Soc. For Microbiology
	PENZES, ZOLTAN ET AL., "Progress Towards the Construction of a Transmissible Gastroenteritis Coronavirus Self-Replicating RNA Using A Two-Layer Expression System," Adv. Exp. Med. Biol., 1998, pp. 319-325, Vol. 440, Plenum Press, New York
	PENZES ET AL., "Construction and expression of a TGEV self-replicating RNA," Poster at the VIIth International Symposium on Coronaviruses and Arteriviruses, May 10-15, 1997, Segovia, Spain
	POLO, STEPHANIE ET AL., "Infectious RNA Transcripts from Full-Length Dengue Virus Type 2 cDNA Clones Made in Yeast," J. Virology, July 1997, pp. 5366-5374, Vol. 71, No. 7, Amer. Soc. For Microbiology
	SUMIYOSHI, HIDEO ET AL., "Infectious Japanese Encephalitis Virus RNA Can Be Synthesized from In Vitro-Ligated cDNA Templates," J. Virology, Sept. 1992, pp. 5425-5431, Vol. 66, No. 9, Amer. Soc. For Microbiology
	TELLIER, RAYMOND ET AL., "Amplification of the full-length hepatitis A virus genome by long reverse transcription-PCR and transcription of infectious RNA directly from the amplicon," PNAS, April 1996, pp. 4370-4373, Vol. 93, Genetics
	TELLIER, RAYMOND ET AL., "Long PCR and Its Application to Hepatitis Viruses: Amplification of Hepatitis A, Hepatitis B, and Hepatitis C Virus Genomes," J. Clin. Microbiol., Dec. 1996, pp. 3085-3091, Vol. 34, No. 12
	THIEL, VOLKER ET AL., "Effective Amplification of 20-kb DNA by Reverse Transcription PCR," Analytical Biochem., 1997, pp. 62-70, Vol. 252, Academic Press
	THIEL, V. ET AL., "Reverse Genetics of Coronaviruses Using Vaccinia Virus Vectors," 2005, pp. 199-227, Vol. 287, Springer-Verlag
✓	YANAGI, MASAYUKI ET AL., "Transcripts from a single full-length CDNA clone of hepatitis C virus are infectious when directly transfected into the liver of a chimpanzee," PNAS, August 1997, pp. 8738-8743, Vol. 94, Medical Sciences

Examiner Signature	/Louise Humphrey/	Date Considered	09/26/2007
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